

AMENDMENTS TO THE DRAWINGS

The attached replacement sheet of drawings includes amendments to Figures 2A, 2B, 2C, 3, 4, 5 and 6, which were amended at the Examiner's request to eliminate reference characters 118 and 318. This attached replacement sheet of drawings replaces the original sheet of drawings.

An annotated or marked-up sheet of drawings is also attached. The annotated sheet of drawings shows the proposed drawing corrections in red ink.

REMARKS

I. Background

The present Amendment is in response to the Examiner's Office Action mailed September 19, 2006. Claim 21 has been amended and no new claims have been added. Claims 17-22 and 36 are now pending.

Reconsideration of the application is respectfully requested in view of the above amendments to the claims and the following remarks. For the Examiner's convenience and reference, Applicant's remarks are presented in the order in which the corresponding issues were raised in the Office Action.

Please note that the following remarks are not intended to be an exhaustive enumeration of the distinctions between any cited references and the claimed invention. Rather, the distinctions identified and discussed below are presented solely by way of example to illustrate some of the differences between the claimed invention and the cited references. In addition, Applicants request that the Examiner carefully review any references discussed below to ensure that Applicants understanding and discussion of the references, if any, is consistent with the Examiner's understanding.

II. Proposed Amendments

Claim 21, the drawings, and the specification were objected to in view of certain formalities. By this amendment, Applicants have amended claim 21 to correct the informality.

The Examiner notes that reference characters 118, 318, L₁, and L₂ are not mentioned in the specification. The Applicant respectfully identifies the characters L₁ and L₂ as already present in the specification as l₁ and l₂, at paragraphs 0055 and 0056, respectively. The reference to l₁ and l₂ in Figures 4 and 5 are supported in that Figures 4 and 5 are variations of Figure 2A and bear the same identifying characters. As requested by the Examiner, the characters 118 and 318 have been removed from the drawings, as shown on the Replacement Sheets.

Further, the Examiner notes that the Applicant has not entered the serial number listed on page 34 of the Application. The Applicant respectfully directs the Examiner to page 3 of the

Second Preliminary Amendment filed by Applicant on December 19, 2005, wherein the requested change was made to paragraph 0081.

Applicants respectfully submit that the amendments to the claims and specification do not introduce new matter and entry thereof is respectfully requested.

III. Rejection on the Merits

A. Rejections Under 35 U.S.C. § 102(b)

Claims 17-19 were rejected under 35 U.S.C. § 102(b) as being anticipated by *Spence et al.* (U.S. Patent No. 6,488,692). Applicants respectfully traverse the rejection because the Office Action has not established a case of anticipation under § 102(b).

According to the applicable law, a claimed invention is anticipated under § 102(b) if it has been "patented or described in a printed publication[.]" 35. U.S.C. § 102(b). Anticipation under § 102 requires "the presence in a single prior art disclosure of all elements of a claimed invention arranged as in that claim." *Sandt Tech., Ltd. v. Resco Metal & Plastics Corp.*, 264 F.3d 1344, 1350 (Fed. Cir. 2001) (citations omitted). "The absence from the reference of any claimed element negates anticipation." *Kloster Speedsteel AB v. Crucible, Inc.*, 793 F.2d 1565, 1571 (Fed. Cir. 1986), *overruled on other grounds by Knorr-Bremse Systeme Fuer Nutzfahrzeuge GmbH v. Dana Corp.*, 383 F.3d 1337 (Fed. Cir. 2004).

Applicant's invention, as recited in claim 17, discloses a device for engaging tissue, comprising an annular-shaped body ***that is movable from a substantially planar configuration towards a transverse configuration extending outside the plane***, with a plurality of looped elements extending about the periphery of the body, a plurality of tines extending from the looped elements towards the central axis in the planar configuration and substantially parallel to the central axis in the transverse configuration, and a spring element between the tines and the looped elements which allows the tips of the tines to be moved away from one another.

Spence does not disclose an annular shaped body that is movable from a substantially planar configuration towards a transverse configuration extending outside the plane. Rather, the ring in *Spence* is able to be "deformed from the oval configuration shown in Fig. 7 with a short axis MSA being a fraction of long axis MLA into a more circular configuration in which the short axis is a significant percentage of the long axis, and then retain its shape until mechanically

deformed again back towards the Fig. 7 configuration.” (Column 8, lines 16-22). In short, the *Spence* ring may be deformed from an oval configuration into a more circular configuration, but that deformation takes place in the same plane, and does not move into a substantially transverse configuration as disclosed in claim 17.

Because *Spence* fails to disclose a ring that is movable from a planar configuration into a substantially transverse configuration, *Spence*, under the law, cannot anticipate claim 17 of the Applicants’ invention. As such, Applicants respectfully request that the rejection of claims 17-19 be withdrawn.

B. Rejections Under 35 U.S.C. § 103

The Examiner rejects claim 20 as being unpatentable over *Spence* in view of *Loshakove, et al.* (U.S. Patent No. 6,726,704). The Examiner also rejects claims 21 and 22 as being unpatentable over *Spence* and *Loshakove*, in further view of *Gifford, et al.* (U.S. Patent No. 5,904,697). Finally, the Examiner rejects claim 36 as being unpatentable over *Spence* and *Loshakove* and *Gifford*. Applicants respectfully traverse the rejections of claims 20, 21 22 and 36 because the Office Action has not established a *prima facie* case of obviousness.

According to the applicable law, a claimed invention is unpatentable for obviousness if the differences between it and the prior art “are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art.” 35 U.S.C. § 103(a) (2005); *Graham v. John Deere Co.*, 383 U.S. 1, 14 (1966); MPEP 2142. Obviousness is a legal question based on underlying factual determinations including: (1) the scope and content of the prior art, including what that prior art teaches explicitly and inherently; (2) the level of ordinary skill in the prior art; (3) the differences between the claimed invention and the prior art; and (4) objective evidence of nonobviousness. *Graham*, 383 U.S. at 17-18; *In re Dembiczak*, 175 F.3d 994, 998 (Fed. Cir. 1999). It is the initial burden of the PTO to demonstrate a *prima facie* case of obviousness, which requires the PTO to show that the relied upon references teach or suggest *all* of the limitations of the claims. MPEP 2142 (emphasis added).

According to MPEP section 2143:

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the

art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991)."

(Emphasis added).

1. Claim 20 as unpatentable over *Spence* in view of *Loshakove*

The Examiner rejects claim 20 as unpatentable over *Spence* in view of *Loshakove*. Applicants respectfully traverse the rejection of claim 20 because the Office Action has not established a *prima facie* case of obviousness.

Spence teaches an "access and cannulation device ... to provide access therethrough via an incision to the interior of a hollow anatomical structure such as a vessel, an organ or the like during surgery." (Abstract). The *Spence* device is comprised of a ring-shaped body, a plurality of arcuate sections, and tines shaped to engage the vessel wall. (Column 8, lines 11-16). As noted previously, the *Spence* device is able to be "deformed from the oval configuration shown in Fig. 7 with a short axis MSA being a fraction of long axis MLA into a more circular configuration in which the short axis is a significant percentage of the long axis, and then retain its shape until mechanically deformed again back towards the Fig. 7 configuration" (*Spence*, column 8, lines 16-22), and not from a planar configuration into a substantially transverse configuration, as required by claim 20.

Merely providing the curved tines disclosed in *Loshakove*, as suggested by the Office Action, will not render claim 20 obvious. Still missing from the combination is the capability of moving from a substantially planar configuration into a substantially transverse configuration. This deficiency in the scope and content of the prior art remains.

Further, *Spence* teaches away from a combination with *Loshakove*. "A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant." *In re Kahn*, 441 F.3d at 990 (quoting *In re Gurley*, 27 F.3d 551, 553 (Fed. Cir. 1994)). *Spence* teaches an access and cannulation device that contains, *inter alia*, "closure sutures pre-installed in the sleeve adjacent to neck portion ... [that] provide rapid closure of the incision once the suture is removed." (Column 10, lines 4-9).

It is the tightening of the suture that pulls the walls of the sleeve together, thus deforming and moving the sides of the ring toward each other, closing the incision. (Column 10, lines 17-19).

In contrast, *Loshakove* discloses a hole closure device that performs the function of closing the incision through a hinge mechanism (Column 2, lines 19-30) or a spring-loaded mechanism that is engaged when spacers are removed from the device. (Column 2, lines 43-51). One of ordinary skill in the art considering *Spence* would not be led to consider *Spence* in combination with *Loshakove*, as the sutures disclosed by *Spence* would obviate the need for the closure mechanisms disclosed by *Loshakove*. There is no evidence that the closure device of *Loshakove* would improve the *Spence* device or resolve some deficiency in *Spence*. Since *Spence* teaches a closure device that may be incompatible with or render unnecessary the closure device of *Loshakove*, *Spence* teaches away from being combined with *Loshakove* in order to arrive at the presently claimed invention.

As this combination would fail to teach or suggest all the limitations of claim 20, the Office Action fails to establish a *prima facie* case of obviousness. As such, Applicants respectfully request the rejection of claim 20 be withdrawn.

2. Claims 21 and 22 as unpatentable over *Spence* and *Loshakove*, in further view of *Gifford*

The Examiner rejects claim 20 as unpatentable over *Spence* and *Loshakove*, in further view of *Gifford*. Applicants respectfully traverse the rejections of claims 21 and 22 because the Office Action has not established a *prima facie* case of obviousness.

As noted previously, the combination of *Spence* and *Loshakove* do not teach or disclose each of the elements of independent claim 20. It necessarily follows that, unless the addition of *Gifford* will provide the missing elements for independent claim 20, this addition cannot render dependent claims 21 and 22 obvious. At a minimum, neither *Spence* nor *Loshakove* teach or suggest an annular-shaped body that is movable from a substantially planar configuration towards a transverse configuration extending outside the plane. The addition of *Gifford* fails to resolve this deficiency in the scope and content of the prior art. As such, the Office Action fails to establish a *prima facie* case of obviousness of claims 21 and 22. As such, Applicants respectfully request the rejection of claims 21 and 22 be withdrawn.

3. Claim 36 as unpatentable over *Spence* and *Loshakove* and *Gifford*

The Examiner rejects claim 36 as unpatentable over *Spence* and *Loshakove* and *Gifford*. The Applicant respectfully traverses the rejection of claim 30 because the Office Action has not established a *prima facie* case of obviousness.


Claim 36 discloses a device for engaging tissue comprised of, *inter alia*, a generally annular-shaped body that is movable from a substantially planar configuration lying generally in the plane towards a transverse configuration extending out of the plane. As noted previously, neither *Spence* nor *Loshakove* teach or suggest this limitation. Further, the addition of *Gifford* to the combination of *Spence* and *Loshakove* fails to resolve this deficiency in the scope and content of the prior art. As such, the Office Action fails to establish a *prima facie* case of obviousness of claim 36. As such, Applicant respectfully requests the rejection of claim 36 be withdrawn.

CONCLUSION

In view of the foregoing, Applicants believe the claims as amended are in allowable form. In the event that the Examiner finds remaining impediment to a prompt allowance of this application that may be clarified through a telephone interview, or which may be overcome by an Examiner's Amendment, the Examiner is requested to contact the undersigned attorney.

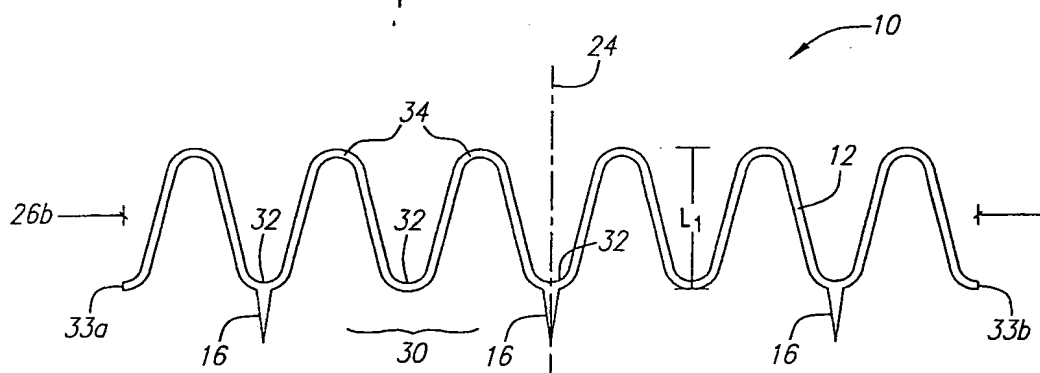
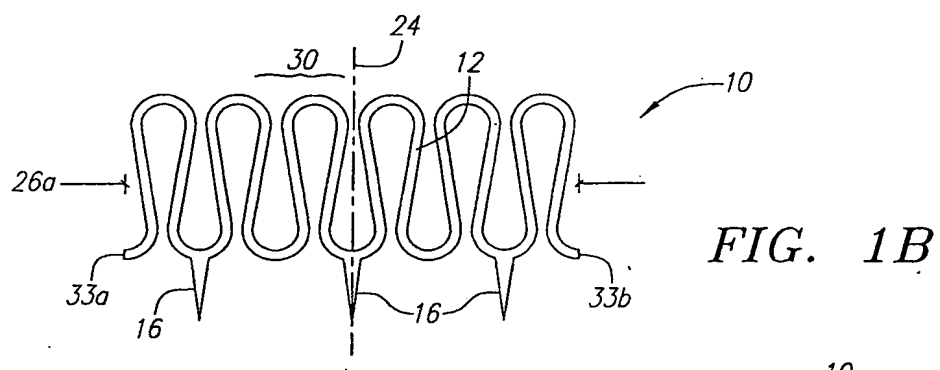
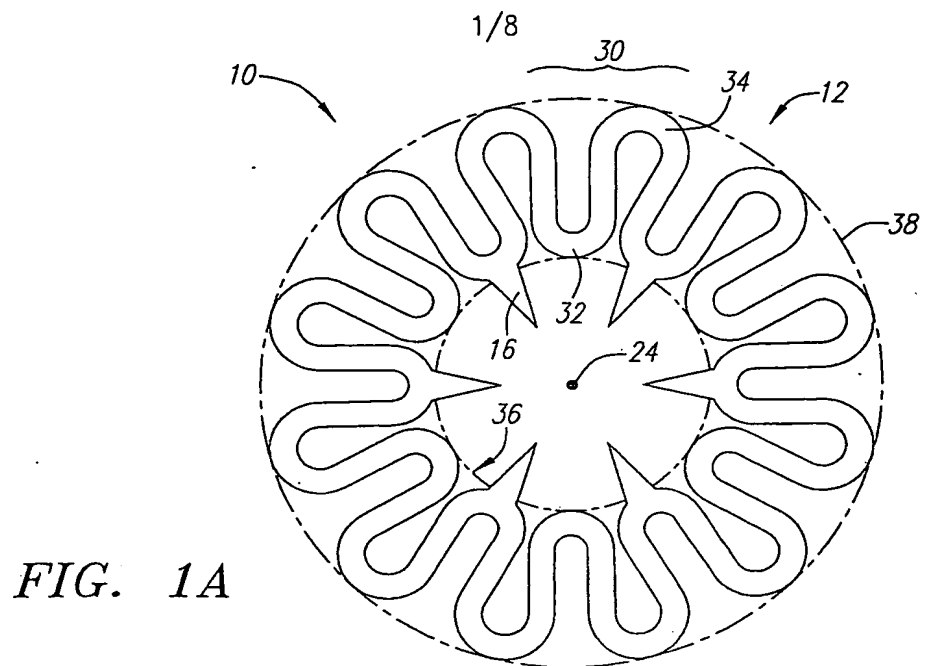
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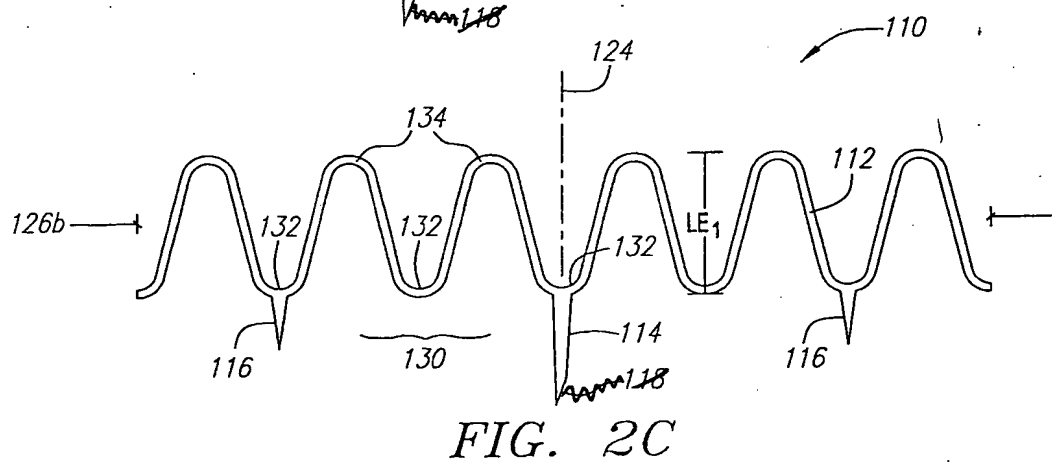
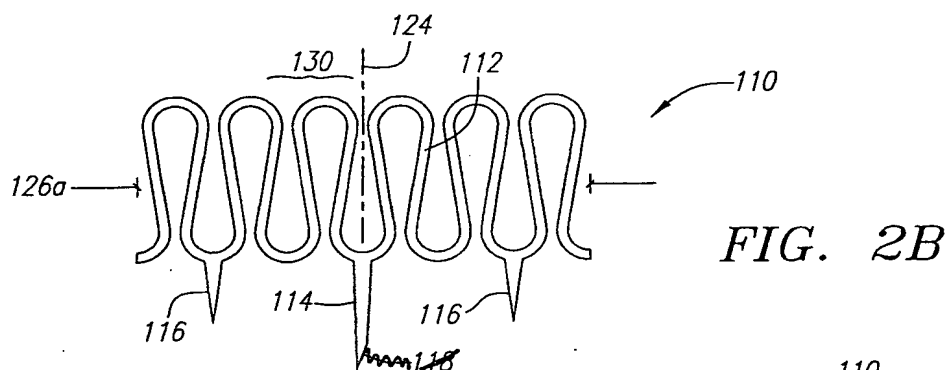
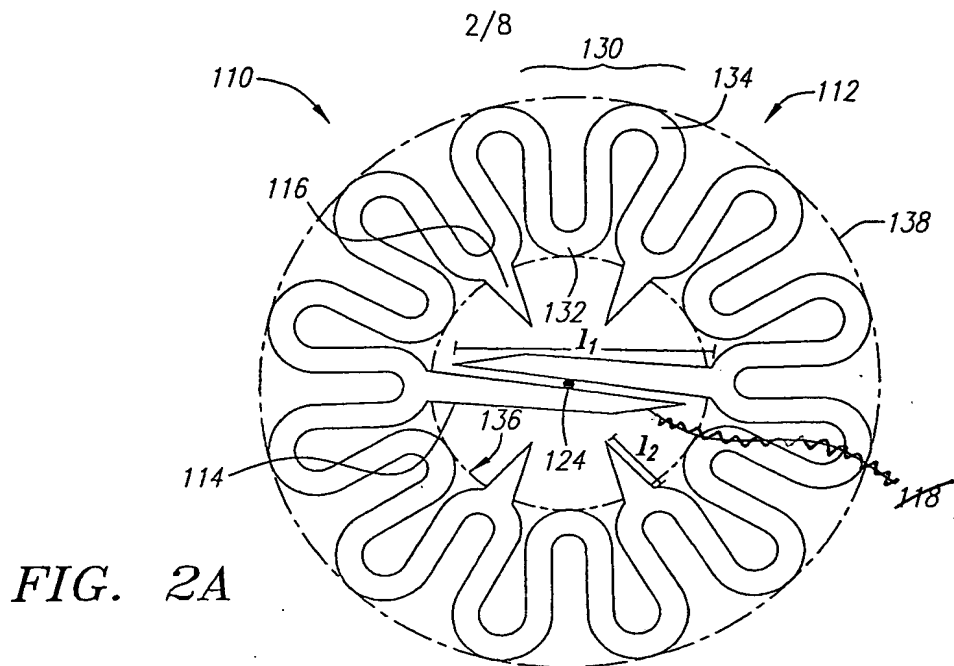
Respectfully submitted,



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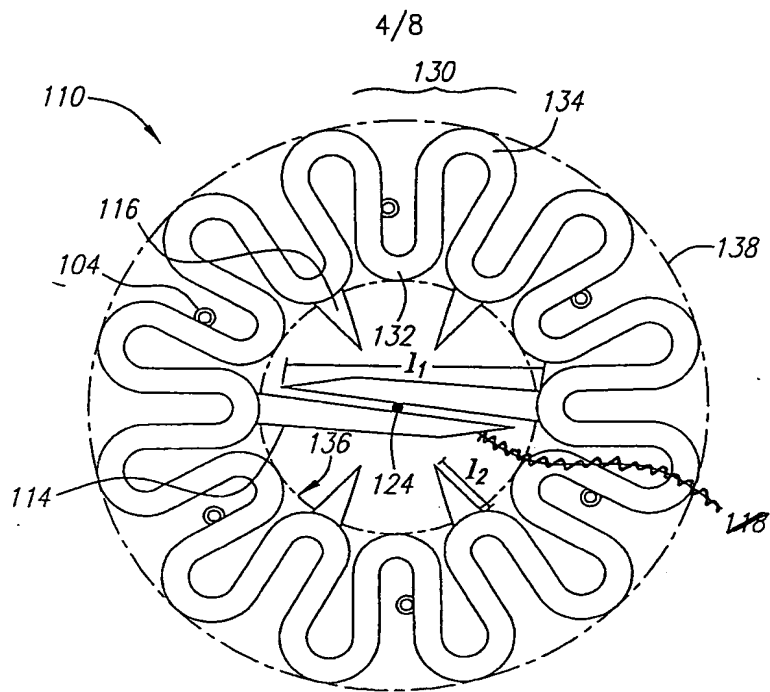


FIG. 5

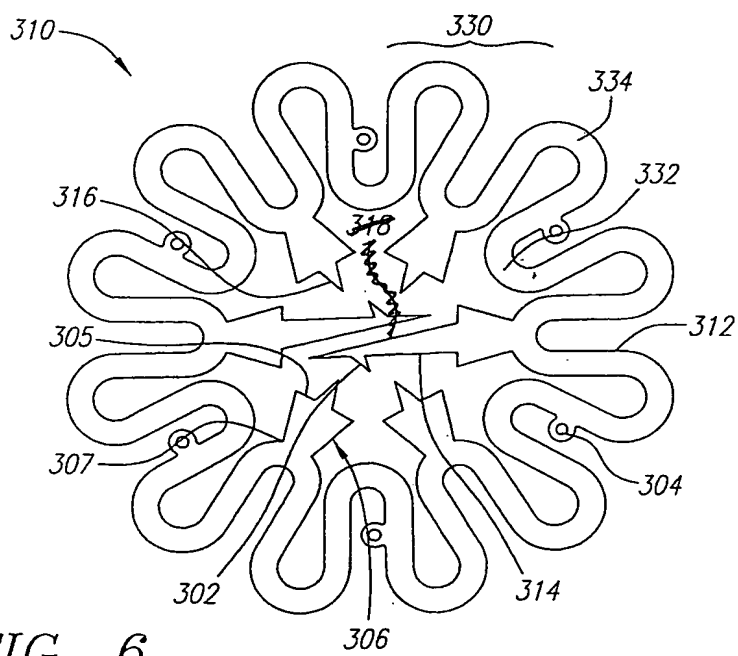
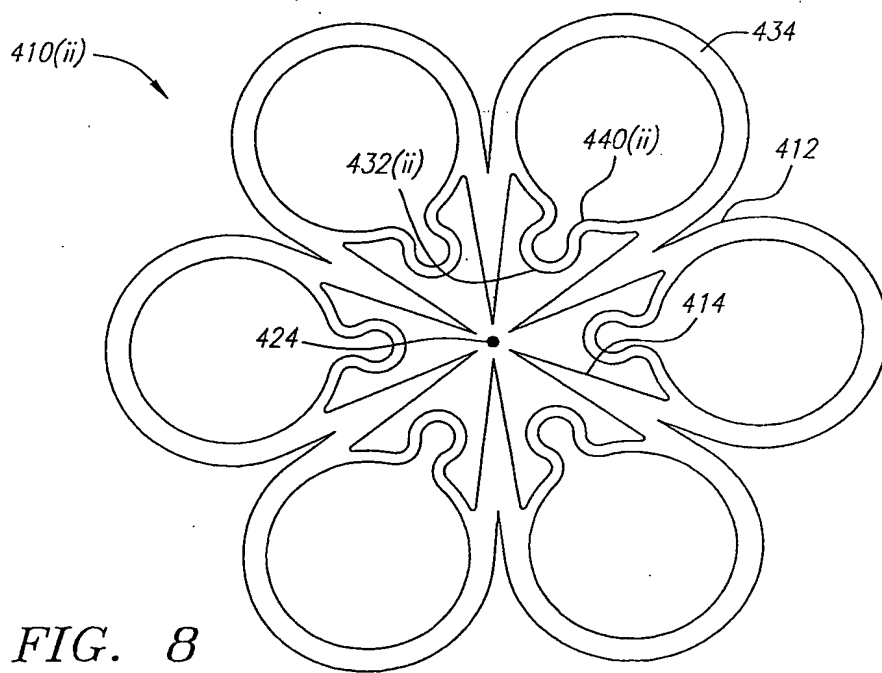
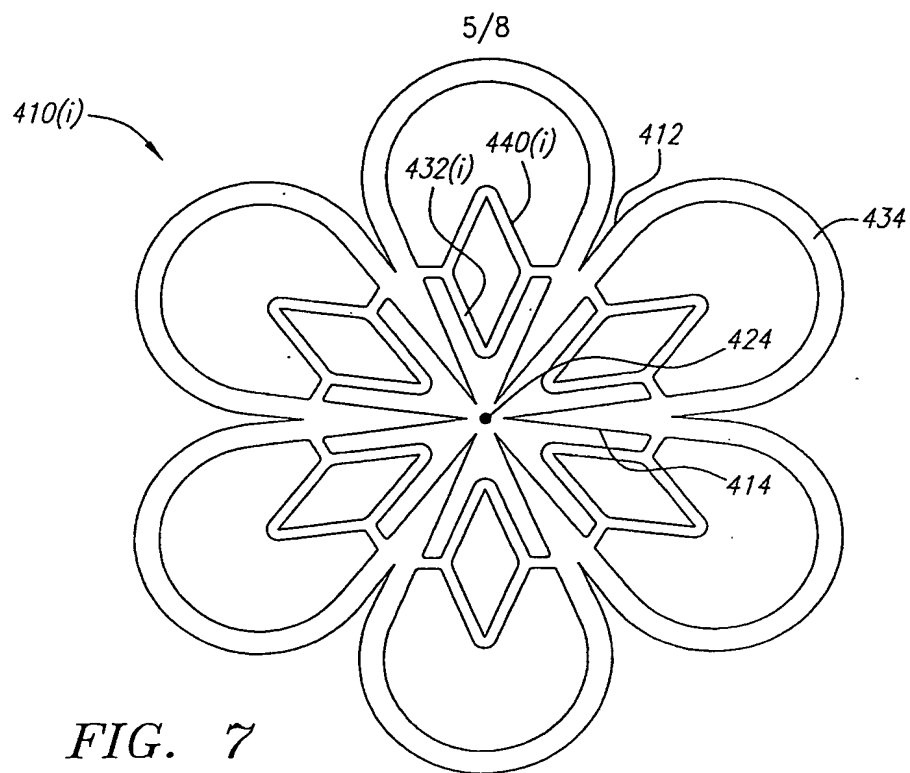


FIG. 6



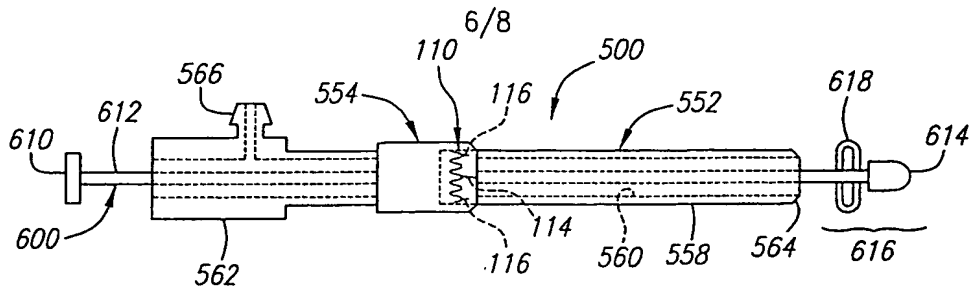


FIG. 9

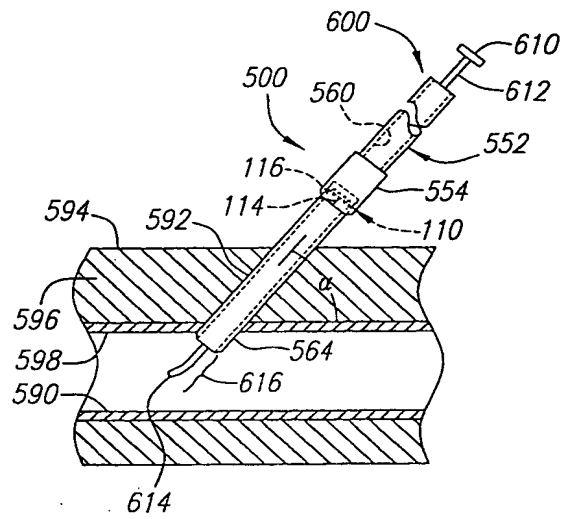


FIG. 10A

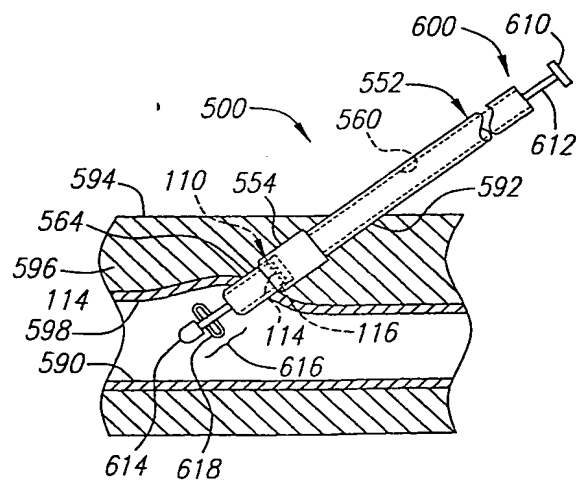


FIG. 10B

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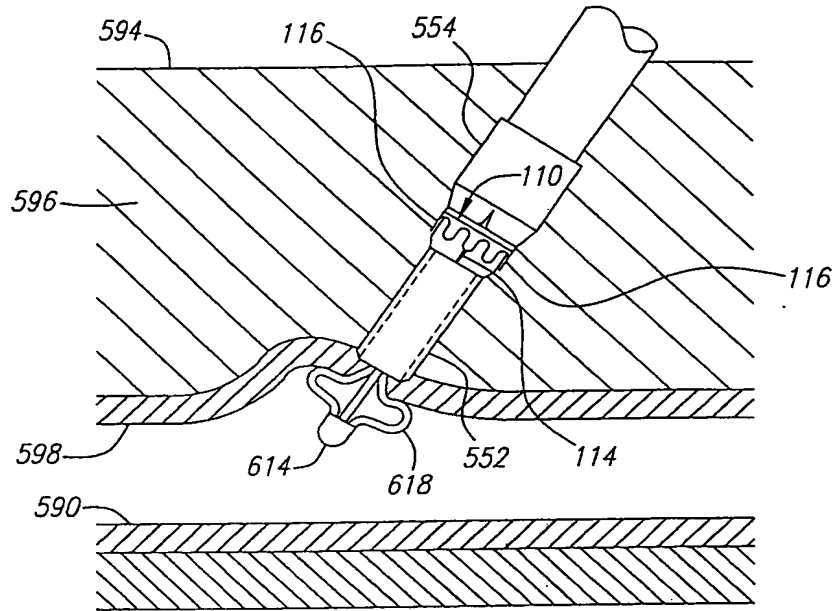


FIG. 10C

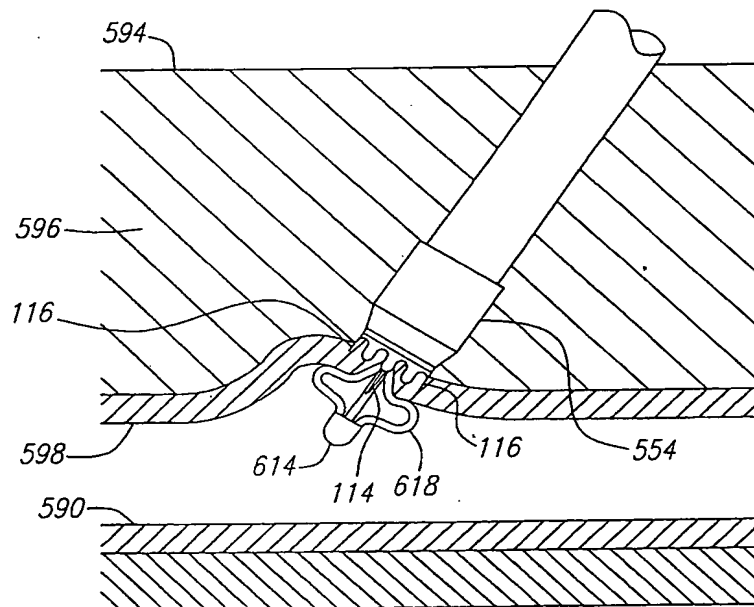


FIG. 10D

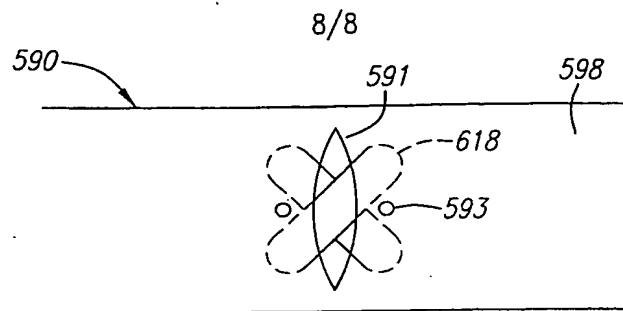


FIG. 11A

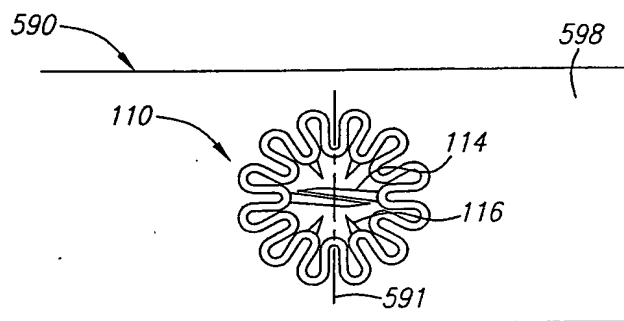


FIG. 11B

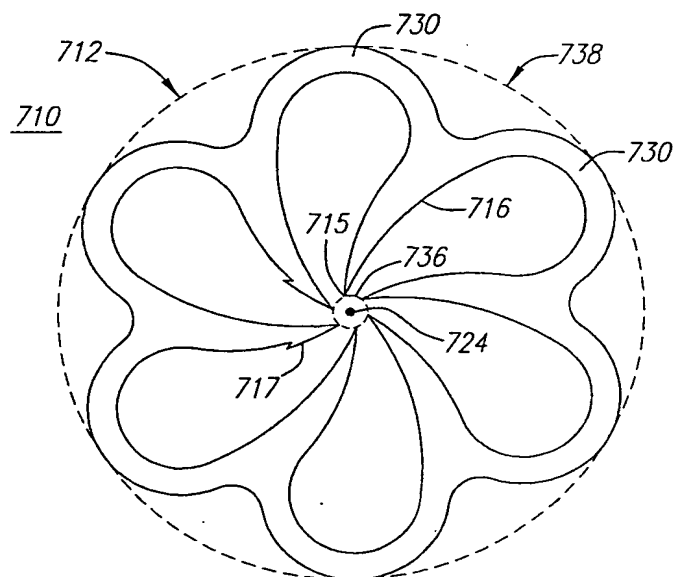


FIG. 12